REMARKS

With entry of this Amendment, claims 1-50 are pending in the application. By this amendment new claims 39-50 have been added. All of the amendments herein are fully supported by the specification, and no new matter has been added to the application.

Compliance of Information Disclosure Statement with 37 CFR 1.98(a)(1)

Applicant notes with appreciation the grant of a teleconference on March 5, 2002 between Examiner Jones and Ms. Groth. Applicant respectfully submits that the Information Disclosure Statement accompanied by Form PTO-1449 submitted March 26, 2001 fully complies with the requirements of 37 CFR 1.98(a)(1). In accordance with the Examiner's suggestion, copies of the March 26, 2001 Information Disclosure Statement, Transmittal Form, Form PTO-1449, and return postcard are enclosed herewith. In view of the foregoing, Applicant respectfully requests entry of those documents into the official file as of the original filing date of March 26, 2001 and withdrawal of the objection on the grounds of a deficient Information Disclosure Statement.

Rejections under 35 U.S.C. §112, first paragraph

Applicant concurs with the Examiner that the specification is enabling for the treatment of breast cancer. Claims 39-50 specifically reciting methods for treating breast cancer have accordingly been added to expedite allowance of this subject matter in the application.

Claims 1, 26, and 33 stand rejected under 35 U.S.C. §112, first paragraph for alleged lack of enablement. Although the Office recognizes that the specification is enabled for the treatment of breast cancer, the Office asserts that the specification fails to provide enablement for the prevention or prophylaxis of breast cancer. Applicant respectfully traverses this rejection.

The enablement requirement of section 112 is satisfied so long as a disclosure contains sufficient information that persons of ordinary skill in the art having the disclosure before them would be able to make and use the invention. *See In re Wands*, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988) (framing the legal standard for enablement under section 112 as a determination of whether one skilled in the art would be able to practice the invention without undue experimentation).

That some experimentation may be required does not preclude enablement so long as the amount of experimentation is not unduly extensive. *See W. L. Gore & Associates, Inc. v. Garlock, Inc.*, 220 U.S.P.Q. 303, 316 (Fed. Cir. 1983). Routine experimentation does not constitute undue experimentation.

> The test [for undue experimentation] is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention.

PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564, 37 U.S.P.Q.2d 1618, 1623 (Fed. Cir. 1996) (quotation and citation omitted).

The key to analyzing "undue experimentation" lies in determining what is "undue," because some trial and error is permissible. *W.L. Gore & Assoc. v. Garlock, Inc.*, 721 F.2d 1540, 1557, 220 U.S.P.Q. 303, 316 (Fed. Cir. 1983) ("Assuming some experimentation were needed, a patent is not invalid because of a need for experimentation. A patent is invalid only when those skilled in the art are required to engage in *undue* experimentation to practice the invention." (cite omitted; emphasis in original)), *cert. denied*, 469 U.S. 851 (1984).

Applicant respectfully submits that the application as filed contains sufficient information that persons of ordinary skill in the art having the disclosure before them would be able to make and use the invention in a manner commensurate with the scope of claims presented for review.

Applicant provides an enabling description pertaining to the prevention and prophylaxis of breast cancer using an oxytocin analogue in, for example, Example II of the application. As set forth on page 36, line 29 to page 37, line 28 of the application as filed:

> [Female rats] at 50 to 52 days of age are subjected to intranasal carbetocin administration at stepwise dosages and frequencies. The carbetocin nasal spray solution will contain commercially available carbetocin in 0.1M $NaH_2PO_4 \cdot H_2O$ buffer, and varying concentrations of polysorbate-80 and nonoxynol-9. For this purpose, stock solutions containing 10:90, 50:50, and 25:75 (wt:wt) polysorbate 80:nonoxynol-9 are prepared and added to

> the spray solution to a final concentration of 0.1% to 0.75% by weight. Nitrous oxide (Union Carbide, New York) is used as a propellant. Formulations A, B, or C of Example I can be used in these studies. The carbetocin therapy is initiated one week before administration of the DMBA, and animals are divided into separate dosage groups and a control group. Exemplary dosages for test animals range between about 0.01 and 5 mg/kg of carbetocin, exclusive of the selected carrier, administered one or more times daily. Mammary carcinoma is induced in the test subjects .
> . . .
>
> Test and control animals are monitored continuously after carbetocin treatment for signs of adverse side effects, including nasal irritation. The subjects are monitored during a period of from about 30 to 85 days following administration of DMBA for determining the incidence of tumor development. Using standard methods, the average number of tumors per animal is determined for test groups protected by selected carbetocin dosages and compared with the average number of tumors per animal in the unprotected control group. Tumor number and size, e.g., as measured with calipers, are determined weekly.

Thus, Applicant respectfully submits that the disclosure enables prevention and prophylaxis of breast cancer using an oxytocin analogue as described, without undue experimentation.

The Examiner relies on the Stein et al. reference (Internal Medicine, 4th ed., Chapters 71-72, pages 699-715 (1994)) as allegedly supporting a conclusion that "[t]he cancer therapy art remains highly unpredictable, and no example exists for efficacy of a single product against tumors generally." In particular, Stein et al. is cited for teaching "that the various types of cancers have different causative agents, involve different cellular mechanisms, and, consequently, differ in treatment protocol."

The prophylactic methods and compositions of the invention, however, specifically target breast cancer--not "tumors generally." Moreover, the Stein et al. article, in fact, teaches that the optimum therapy for breast cancer is still evolving. Modifications to the current approaches to breast cancer therapies must take into account the results of ongoing clinical trials (page 709). Table 72-1 of that publication illustrates the decline in the rate of mortality as a direct result of systematic clinical trials that have tested various laboratory advances and hypotheses. Specifically, the five-year survival rate for breast cancer patients increased at least 10% for patients diagnosed in 1981-1986 versus patients diagnosed in 1970-1973.

One such advance noted by Stein et al. is the search for a single, inexpensive blood test for the early detection of cancer. While at the time of publication of the Stein et al. reference no tumor markers for attaining that goal existed, Applicant thoroughly details the recent advances in the identification, detection, and measurement of breast cancer markers (page 10, line 16 – page 14, line 26 of the application). Specifically, powerful new technology has been developed that allows non-invasive breast cancer marker assays utilizing oxytocin-induced mammary fluid samples to be conducted. Fluid samples within the mammary glands themselves are expected to contain much higher and more biologically relevant levels of breast cancer markers than serum, since 80-90% of all breast cancers occur within the intraductal epithelium of the mammary glands. As noted by the Applicant at lines 10-15 of page 13 of the application, fluid within the breast ducts is expected to contain an assemblage and concentration of hormones, growth factors, and other potential markers comparable to those secreted by, or acting upon, the surrounding cells of the alveolar-ductal system. Likewise, mammary fluid is expected to contain cells and solid cellular debris or products that can be used in cytological or immunological assays to evaluate intracellular or cell surface markers that may not be detectable in the liquid fraction of mammary fluid.

In view of these technological advances as disclosed in the present application, one of skill in the art would readily be able to identify candidates for the prevention or prophylaxis of breast cancer to practice the claimed invention. Any experimentation necessary would be no more than routine experimentation, which, as discussed above, does not constitute undue experimentation.

Accordingly, Applicant respectfully requests that the rejection of claims 1, 26, and 33 under 35 U.S.C. §112, first paragraph for alleged lack of enablement be withdrawn.

Patentability Under 35 U.S.C. §102

Claims 1-12 and 26-33 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Cassoni et al. (Virchows Archive (1994) 425:467-472). In particular, the Office relies on Cassoni et al. as teaching "the administration of oxytocin or with an analog of oxytocin to inhibit breast cancer growth." Applicant respectfully traverses this rejection.

Applicant's method claims 1-12 recite methods for prophylaxis or treatment of breast cancer in a mammalian patient that involves "administering to said patient a therapeutically effective amount of one or more compound (s) selected from the group consisting of carbetocin and other long-acting oxytocin analogues in a pharmaceutically acceptable carrier sufficient to inhibit initiation or growth of breast cancer in said patient." Applicant's composition claims 26-32 pharmaceutical compositions for prophylaxis or treatment of breast cancer in a mammalian patient including "a therapeutically effective amount of one or more oxytocin analogue(s) selected from the group consisting of carbetocin and other long-acting oxytocin analogues in a pharmaceutically acceptable carrier" to inhibit initiation or growth of breast cancer in said patient. As explained in the specification at page 6, lines 7-13 and at page 15, line 25 to page 16, line 4, carbetocin is a "long-acting oxytocin analog," having a half-life 4-10 times longer than that of oxytocin. Thus, the language "long-acting oxytocin analog" excludes oxytocin.

Applicant's pending composition claim 33 recites a medicament suspension or powder for nasal administration to treat or prevent breast cancer having carbetocin and a powder of one or more cation exchange resins and/or one or more absorbent resins.

To anticipate a claim, a prior art reference must disclose every feature of the claimed invention, either explicitly or inherently. *See Glaxo v. Novopharm, Ltd.*, 334 U.S.P.Q. 2d 1565 (Fed Cir. 1995).

Cassoni reports the *in vitro* administration of oxytocin and the oxytocin analogue F314 to breast cancer cells. Cassoni reports that F314 "caused a strong and significant inhibition of [estrogen-independent] MDA-MB231 cell growth" at relatively high concentrations. *See* Figure 1C of Cassoni, page 468. Cassoni, however, fails to teach or even suggest the administration of a *long-acting* oxytocin analogue in a pharmaceutically acceptable carrier to a mammalian patient.

The Cassoni disclosure also fails to teach or suggest the administration of carbetocin as specifically set forth in pending claim 2. The Cassoni disclosure also lacks any teaching or suggestion of the modes of administration to the patient, as recited in claims 3 and 4, or formulations of the oxytocin analogues, as recited in claims 5-8.

Cassoni additionally fails to teach or suggest a dose of at least one microgram, as set forth in claim 9, or daily administration of the oxytocin analogue as set forth in claim 10.

The disclosure of Cassoni further fails to teach or suggest the step of administering tamoxifen and/or raloxifen to the patient in an amount sufficient to inhibit initiation or growth of estrogen-dependent breast cancer in addition to administering an oxytocin analogue, as set forth in pending claims 11 and 12.

Regarding the composition claims 26-32, Cassoni fails to teach or suggest a therapeutically effective amount of a long-acting oxytocin analogue sufficient to inhibit initiation or growth of breast cancer in a mammalian patient or a pharmaceutically acceptable carrier. As previously mentioned, the Cassoni disclosure is devoid of any teaching or suggestion of carbetocin, as set forth in claim 27. Additionally, Cassoni fails to teach or suggest formulation of the oxytocin analogue for intranasal or intrapulmonary administration, as recited in claims 28-29. Cassoni further fails to teach or suggest an oxytocin analogue formulated with an excipient, as set forth in claim 30, or a dosage form containing at least one microgram of the oxytocin analogue, as set forth in claim 31.

The Cassoni disclosure further fails to provide any teaching or suggestion of the pharmaceutical composition recited in claim 32, which includes an oxytocin analogue and tamoxifen or raloxifen in an amount sufficient to inhibit initiation or growth of estrogen-dependent breast cancer. Rather, Cassoni reports the *in vitro* administration of the oxytocin analogue F314 alone to estrogen-dependent MCF7 cells.

Cassoni is further devoid of any teaching or suggestion of the medicament suspension or powder for intranasal administration, as set forth in claim 33, including carbetocin and one or more cation exchange resins and/or one or more absorbent resins.

For the foregoing reasons, Applicant respectfully submits that the Cassoni reference is facially deficient as an anticipatory reference of the subject matter presented in claims 1-12 and 26-33, and that the rejection of these claims under 35 U.S.C. §102(b) should therefore be withdrawn.

Claims 13-25 and 34-38 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Boer et al. (Peptides (1992) 13:1083-1085) or alternatively by Leckman et al. (Psychoneuroendocrinology (1994) 19(8):723-749). Applicant's method claims 13-25 recite methods for prophylaxis or treatment of a psychiatric disorder in a mammalian

patient that involves "administering to said patient a therapeutically effective amount of one or more compound(s) selected from the group consisting of carbetocin and other long-acting oxytocin analogues in a pharmaceutically acceptable carrier sufficient to alleviate an obsessive-compulsive behavior of said disorder in said patient." Applicant's composition claims 34-38 recite pharmaceutical compositions for prophylaxis or treatment of a psychiatric disorder in a mammalian patient having "a therapeutically effective amount of one or more oxytocin analogue(s) selected from the group consisting of carbetocin and other long-acting oxytocin analogues in a pharmaceutically acceptable carrier, wherein said composition is sufficient to alleviate at least one symptom of said psychiatric disorder in said patient."

Turning first to Boer et al., the Office relies on this reference for allegedly teaching the utilization of "oxytocin to treat the psychiatric disease of obsessive-compulsive disorder." However, as noted above the present invention (see, e.g., method claims 13-25 and composition claims 34-38) involves the novel employment of carbetocin and/or another long-acting oxytocin analogue(s), and the administration thereof to a mammalian patient. Boer is completely devoid of any teaching or suggestion of such a composition having a long-acting oxytocin *analogue* or its administration to a mammalian patient. The reference therefore clearly fails to teach every aspect of Applicant's claimed methods. On this basis, withdrawal of the rejection of claims 13-25 and 34-38 under 35 U.S.C. §102(b) over Boer is earnestly solicited.

With regard to the Leckman et al. reference, the Office relies on this disclosure as allegedly teaching "the administration of oxytocin to treat the psychiatric disease of obsessive compulsive disorder." Leckman reports a proposed relationship between oxytocin dysfunction and obsessive-compulsive disorder. Specifically, Leckman postulates on page 739 that "[p]atients with [oxytocin]-related OCD might also be expected to benefit from treatment with centrally active [oxytocin] *antagonists* (none of which are currently available...)." However, in contrast to Applicant's invention as set forth in claims 13-25 and 34-38, Leckman clearly fails to teach, or even suggest, a pharmaceutical composition including one or more of carbetocin and other *long-acting oxytocin analogues*, and the administration thereof, to effectively treat any psychiatric disorder in a mammalian patient. Applicant accordingly requests reconsideration and

withdrawal of the rejection of claims 13-25 and 34-38 under 35 U.S.C. §102(b) over Leckman.

Patentability under 35 U.S.C. §103

Claims 1-38 stand rejected under 35 U.S.C §103(a) as allegedly unpatentable over Cassoni et al. in view of Lipton et al. (J. Endocr. (1984) 103:383-388). Applicant respectively traverses the rejection under 35 U.S.C. § 103 because the subject matter of claims 1-38 is neither disclosed nor suggested by the collective teachings of the Cassoni et al. and Lipton et al. references.

Cassoni is cited for allegedly teaching "the administration of oxytocin or with an analog of oxytocin to inhibit breast cancer growth." The Office further cites Lipton as allegedly teaching "the administration of tamoxifen or oestradiol to treat breast cancer." The Office argues that "[i]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . . [T]he idea of combining them flows logically from their having been individually taught in the prior art." The Office further asserts that "it would have been obvious to one having ordinary skill in the art to simply combine these two prior art references since both compounds are already known to treat the same ailment, specifically breast cancer. In addition, the determination of a mode of administration, such as intranasally, is well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine optimum modes of administration in order to get the maximum effect of the drug."

Regarding composition claims 26-38, the Office further argues that "[i]t is obvious to combine known substances in order to generate a new composition that is known to treat the very same ailment...."

To establish a *prima facie* case of obviousness, three requirements must be satisfied: first there must be some suggestion or motivation to modify the reference or to combine the reference teachings; second, there must be a reasonable expectation of success for achieving the claimed invention and its particular results; and, third, the prior art references must teach or suggest all the claim limitations. *See In re Vaeck*, 20 U.S.P.Q. 2d 1438 (Fed. Cir. 1991).

Applicant first notes that claims 13-25 recite methods for prophylaxis or treatment of a *psychiatric disorder* involving the administration of a therapeutically effective amount of one or more of carbetocin and other long-acting oxytocin analogues in a pharmaceutically acceptable carrier sufficient to alleviate the subject disorder in the patient. Additionally, claims 34-38 recite pharmaceutical compositions for prophylaxis or treatment of a psychiatric disorder in a mammalian patient having a therapeutically effective amount of one or more of carbetocin and other long-acting oxytocin analogues in a pharmaceutically acceptable carrier sufficient to alleviate at least one symptom of the psychiatric disorder.

Applicant respectfully submits that both Cassoni and Lipton are completely devoid of any teaching or suggestion to administer one or more oxytocin analogues to a mammalian patient sufficient to alleviate at least one symptom of a *psychiatric disorder* of the patient. Furthermore, Applicant respectfully submits that neither Cassoni nor Lipton teaches or suggests a pharmaceutical composition including a therapeutically effective amount of one or more of carbetocin and other long-acting oxytocin analogues in a pharmaceutically acceptable carrier sufficient to alleviate *an obsessive-compulsive behavior of a psychiatric disorder* of a mammalian patient. As such, Applicant respectfully submits that the proposed combination of Cassoni in view of Lipton is not suggested, nor would such hypothetical combination yield the subject matter and effective results set forth in claims 13-25 and 34-38. Accordingly, it is respectfully urged that the rejection claims 13-25 and 34-38 under 35 U.S.C. §103(a) over Cassoni in view of Lipton be withdrawn.

Turning to claims 1-12 and 26-33, the instant record fails to establish sufficient motivation to combine Cassoni and Lipton. The importance of the requirement of a motivation to combine prior art references was recently explained by the Federal Circuit, as follows:

> When patentablity turns on the question of obviousness, the search for and analysis of the prior art includes evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the references relied on as evidence of obviousness.... "The factual inquiry whether to combine references must be thorough and searching." It must be based on objective evidence of record. This

> precedent has been reinforced in myriad decisions, and cannot be dispensed with.

In re Sang Su Lee, No. 00-1158 (Fed. Cir. Jan. 18, 2002) (citations omitted). In the present case, the Office's conclusory statement that proposed modifications of the prior art would have been "well within the ordinary skill of the art at the time the claimed invention was made" is not sufficient to establish a *prima facie* case of obviousness--without some specific, objective reason to combine the cited teachings of the references. *Ex parte Levengood*, 28 U.S.P.Q. 2d 1300 (Bd. Pat. App.& Inter. 1993). *See also In re Katzab*, 55 U.S.P.Q. 2d 1313, 1318 (Fed. Cir. 2000); *Al-Site Corp. v. VSI Int'l Inc.*, 50 U.S.P.Q. 2d 1161 (Fed. Cir. 1999). A general assertion that individual components of a claimed invention may have been know by skilled artisans is not sufficient in this context.

Moreover, a prior art reference must be considered in its entirety, including disclosures that would teach away from the claimed invention. *See W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 220 U.S.P.Q. 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). In the instant case, Cassoni reports that no significant effect of oxytocin on the proliferation rate of MCF7 cells was observed. *See* Figure 1D of Cassoni, page 468. Cassoni notes previous reports that underscore the uncertainty regarding possible effects of oxytocin on breast cell growth, differentiation, and survival. Specifically, Cassoni emphasizes (at page 471, paragraph bridging columns 1 and 2) that Taylor et al. (Cancer Res. (1990) 50:7882-7886) found a significant *enhancement* of the growth rate of MCF7 cells as a result of oxytocin administration at low concentrations in the range of 10^{-9} to 10^{-12} M.

Based on these and other teachings (as noted in the application at page 4, lines 5-24), conflicting reports at the time of the present invention gave rise to substantially uncertainty regarding the potential utility of oxytocin, oxytocin analogs, and other hormonal factors as therapeutic agents for successful prophylaxis and treatment of breast cancer. Because the complex roles of these diverse agents remained undefined, the record fails to establish a reasonable expectation of success to practice the instantly claimed invention to obtain the particular results described by Applicant.

Further supporting Applicant's position, Lipton teaches that the administration of tamoxifen or oestradiol-17ß *inhibits* responses stimulated by oxytocin. *See* Figure 1 of Lipton, page 385; Figure 4 of Lipton, page 386. Thus, Lipton teaches directly away from the proposed combination based on Cassoni to achieve a combined effect of estradiol or tamoxifen with oxytocin on breast cancer cell growth. Accordingly, one having ordinary skill in the art would not be motivated to combine the teachings of Lipton with that of Cassoni to achieve a synergistic effect in the prophylaxis or treatment of breast cancer.

Considering these facts and comments, it is respectfully urged that the rejection of claims 1-38 under 35 U.S.C. §103(a) over Cassoni et al. in view of Lipton et al. be withdrawn.

CONCLUSION

In view of the foregoing, Applicant believes that all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-332-1380.

Attached hereto is a marked-up version showing changes made to the claims by the current amendment. The attached page is captioned "**Version with markings to show changes made.**"

Date: March 18, 2007

Respectfully submitted,

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Attachments

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

New claims 39-50 have been added. All currently pending claims are shown below:

1. A method for prophylaxis or treatment of breast cancer in a mammalian patient comprising administering to said patient a therapeutically effective amount of one or more compound(s) selected from the group consisting of carbetocin and other long-acting oxytocin analogues in a pharmaceutically acceptable carrier sufficient to inhibit initiation or growth of breast cancer in said patient.

2. The method of claim 1, wherein said one or more oxytocin analogue(s) comprises carbetocin.

3. The method of claim 1, wherein said one or more oxytocin analogue(s) is/are administered to said patient by a mode of administration selected from intramuscular, intravenous, intranasal, intrapulmonary, subcutaneous, parenteral, oral, or transdermal delivery.

4. The method of claim 3, wherein said one or more oxytocin analogue(s) is/are administered to said patient intranasally.

5. The method of claim 3, wherein said one or more oxytocin analogue(s) is/are formulated in said carrier for intranasal or intrapulmonary administration.

6. The method of claim 5, wherein said one or more oxytocin analogue(s) is/are formulated in a powder or aqueous formulation for intranasal delivery.

7. The method of claim 6, wherein said one or more oxytocin analogue(s) is/are combined in an aqueous formulation with one or more excipients selected from the group consisting of nonoxynol-9, laureth-9, poloxamer-124, octoxynol-9, lauramide DEA, chlorobutanol, glycerol, citric acid, sodium phosphate, methyl paraben, propyl paraben, sorbitol, sodium chloride, and/or sodium acetate for intranasal delivery.

8. The method of claim 6, wherein said carbetocin is formulated with a nonionic surfactant and polysorbate-80 in an aqueous formulation for intranasal delivery.

9. The method of claim 1, wherein said one or more oxytocin analogue(s) is/are administered in a dose of at least one microgram.

10. The method of claim 1, wherein said one or more oxytocin analogue(s) is/are administered daily in an intranasal formulation.

11. The method of claim 1, further comprising administering tamoxifen and/or raloxifene to said patient in an amount sufficient to inhibit initiation or growth of estrogen-dependent breast cancer in said patient.

12. The method of claim 11, wherein said one or more oxytocin analogue(s) and said tamoxifen and/or raloxifene are administered simultaneously as a mixture.

13. A method for prophylaxis or treatment of a psychiatric disorder in a mammalian patient comprising administering to said patient a therapeutically effective amount of one or more compound(s) selected from the group consisting of carbetocin and other long-acting oxytocin analogues in a pharmaceutically acceptable carrier sufficient to alleviate an obsessive-compulsive behavior of said disorder in said patient.

14. The method of claim 13, wherein said psychiatric disorder is obsessive compulsive disorder, Praeder Willi syndrome or autism.

15. The method of claim 13, wherein said one or more oxytocin analogue(s) comprises carbetocin.

16. The method of claim 13, wherein said one or more oxytocin analogue(s) is/are administered to said patient by a mode of administration selected from intramuscular, intravenous, intranasal, intrapulmonary, subcutaneous, parenteral, oral, and transdermal delivery.

17. The method of claim 16, wherein said one or more oxytocin analogue(s) is/are administered to said patient intranasally.

18. The method of claim 16, wherein said one or more oxytocin analogue(s) is/are formulated in said carrier for intranasal or intrapulmonary administration.

19. The method of claim 18, wherein said one or more oxytocin analogue(s) is/are formulated in a powder or aqueous formulation for intranasal delivery.

20. The method of claim 19, wherein said one or more oxytocin analogue(s) is/are combined in an aqueous formulation with one or more excipients selected from the group consisting of nonoxynol-9, laureth-9, poloxamer-124, octoxynol-9, lauramide DEA, chlorobutanol, glycerol, citric acid, sodium phosphate, methyl paraben, propyl paraben, sorbitol, sodium chloride, and/or sodium acetate for intranasal delivery.

21. The method of claim 19, wherein said carbetocin is formulated with a nonionic surfactant and polysorbate-80 in an aqueous formulation for intranasal delivery.

22. The method of claim 13, wherein said one or more oxytocin analogue(s) is/are administered in a dose of at least one microgram.

23. The method of claim 13, wherein said one or more oxytocin analogue(s) is/are administered daily in an intranasal formulation.

24. The method of claim 13, further comprising administering a selective serotonin reuptake inhibitor or serotonin reuptake inhibitor to said patient in an amount sufficient to alleviate an obsessive-compulsive behavior in said patient.

25. The method of claim 24, wherein said one or more oxytocin analogue(s) and said selective serotonin reuptake inhibitor are administered simultaneously as a mixture.

26. A pharmaceutical composition for prophylaxis or treatment of breast cancer in a mammalian patient comprising a therapeutically effective amount of one or more oxytocin analogue(s) selected from the group consisting of carbetocin and other long-acting oxytocin analogues in a pharmaceutically acceptable carrier, wherein said composition is sufficient to inhibit initiation or growth of breast cancer in said patient.

27. The pharmaceutical composition of claim 26, wherein said one or more oxytocin analogue(s) comprises carbetocin.

28. The pharmaceutical composition of claim 26, wherein said one or more oxytocin analogue(s) is/are formulated in said carrier for intranasal or intrapulmonary administration.

29. The pharmaceutical composition of claim 26, wherein said one or more oxytocin analogue(s) is/are formulated in a powder or aqueous formulation for intranasal delivery.

30. The pharmaceutical composition of claim 26, wherein said one or more oxytocin analogue(s) is/are combined in an aqueous formulation with one or more excipients selected from the group consisting of nonoxynol-9, laureth-9, poloxamer-124, octoxynol-9, lauramide DEA, chlorobutanol, glycerol, citric acid, sodium phosphate, methyl paraben, propyl paraben, sorbitol, sodium chloride, and/or sodium acetate for intranasal delivery.

31. The pharmaceutical composition of claim 26, prepared in a unit dosage form containing at least one microgram of said one or more oxytocin analogue(s).

32. The pharmaceutical composition of claim 26, further comprising tamoxifen and/or raloxifen in an amount sufficient to inhibit initiation or growth of estrogen-dependent breast cancer in said patient.

33. A medicament suspension or powder for nasal administration to treat or prevent breast cancer comprising carbetocin and a powder of one or more cation exchange resins and/or one or more adsorbent resins.

34. A pharmaceutical composition for prophylaxis or treatment of a psychiatric disorder in a mammalian patient comprising a therapeutically effective amount of one or more oxytocin analogue(s) selected from the group consisting of carbetocin and other long-acting oxytocin analogues in a pharmaceutically acceptable

carrier, wherein said composition is sufficient to alleviate at least one symptom of said psychiatric disorder in said patient.

35. The pharmaceutical composition of claim 34, wherein said one or more oxytocin analogue(s) comprises carbetocin.

36. The pharmaceutical composition of claim 34, wherein said one or more oxytocin analogue(s) is/are formulated in said carrier for intranasal or intrapulmonary administration.

37. The pharmaceutical composition of claim 34, wherein said one or more oxytocin analogue(s) is/are formulated in a powder or aqueous formulation for intranasal delivery.

38. The pharmaceutical composition of claim 34, further comprising a selective serotonin reuptake inhibitor or serotonin reuptake inhibitor.

Please add the following new claims:

39. (New) A method for treatment of breast cancer in a mammalian patient comprising administering to said patient a therapeutically effective amount of one or more compound(s) selected from the group consisting of carbetocin and other long-acting oxytocin analogues in a pharmaceutically acceptable carrier sufficient to inhibit growth of breast cancer in said patient.

40. (New) The method of claim 39, wherein said one or more oxytocin analogue(s) comprises carbetocin.

41. (New) The method of claim 39, wherein said one or more oxytocin analogue(s) is/are administered to said patient by a mode of administration selected from intramuscular, intravenous, intranasal, intrapulmonary, subcutaneous, parenteral, oral, or transdermal delivery.

42. (New) The method of claim 41, wherein said one or more oxytocin analogue(s) is/are administered to said patient intranasally.

43. (New) The method of claim 41, wherein said one or more oxytocin analogue(s) is/are formulated in said carrier for intranasal or intrapulmonary administration.

44. (New) The method of claim 43, wherein said one or more oxytocin analogue(s) is/are formulated in a powder or aqueous formulation for intranasal delivery.

45. (New) The method of claim 44, wherein said one or more oxytocin analogue(s) is/are combined in an aqueous formulation with one or more excipients selected from the group consisting of nonoxynol-9, laureth-9, poloxamer-124, octoxynol-9, lauramide DEA, chlorobutanol, glycerol, citric acid, sodium phosphate, methyl paraben, propyl paraben, sorbitol, sodium chloride, and/or sodium acetate for intranasal delivery.

46. (New) The method of claim 44, wherein said carbetocin is formulated with a nonionic surfactant and polysorbate-80 in an aqueous formulation for intranasal delivery.

47. (New) The method of claim 39, wherein said one or more oxytocin analogue(s) is/are administered in a dose of at least one microgram.

48. (New) The method of claim 39, wherein said one or more oxytocin analogue(s) is/are administered daily in an intranasal formulation.

49. (New) The method of claim 39, further comprising administering tamoxifen and/or raloxifen to said patient in an amount sufficient to inhibit growth of estrogen-dependent breast cancer in said patient.

50. (New) The method of claim 49, wherein said one or more oxytocin analogue(s) and said tamoxifen and/or raloxifene are administered simultaneously as a mixture.